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510(K) Summary

Submitter: Jong Sup, Chung
Dalim Tissen Co., Ltd
3-5th Fl. Yonnam Bldg., 383-93 Yonnam-dong, Mapo-gu, Seoul, South Korea

Official correspondent: April Lee
Kodent Inc.
325 N. Puente st. Unit B
Brea, CA 92821
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Device Information
Trade Name: Collagen Wound Dressing
Common Name: Wound Dressing
Classification Name: Dressing, Wound, Collagen
Product Code: KGN
Regulation Number: N / A
Device Class: Class II

Date Prepared: 5/21/2012

General Description

Collagen Wound Dressing (Absorbable Collagen Membrane) is a sterile, pliable porous and dense wound dressing made of highly purified collagen derived from porcine skin. It is crosslinked using 1-ethyl-3-(3-dimethyl aminopropyl) carbodiimide (EDC) for the resistance to enzymatic degradation. Collagen Wound Dressing is completely absorbable and highly biocompatible. Collagen Wound Dressing is composed of porous sponge layer for the wound surface and dense film layer for protecting wound from outside.

Indication for Use

Collagen Wound Dressing is intended use for management of partial and full-thickness wounds including: pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers, tunneled / undermined wounds, surgical wound (donor sites / grafts, post-moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), draining wounds.

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Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- TheraForm™ Standard / Sheet manufactured by Sewon Cellontech (K090812)

	Subject Device	Predicate Device
Company	Dalim Tissen Co., Ltd	Sewon Cellontech Co., Ltd.
Device Name	Collagen Wound Dressing	TheraForm™ Standard / Sheet
510(k) Number	N/A	K090812
Device Classification Name	Wound Dressing	Wound Dressing
Product Code	KGN	KGN
Regulation Number	Unclassified	Unclassified
Intended Use	Same as predicate device	Partial and full-thickness wounds -Pressure ulcers -Venous ulcers -Diabetic ulcers -Chronic ulcers -Tunneled / undermined wounds -Surgical wounds (donor sites / grafts, postmoh's surgery, post-laser surgery, podiatric, wound dehiscence) -Trauma wounds (abrasions, lacerations, second -degree bums, and skin tears) -Draining wounds
Description	Collagen Wound Dressing (Absorbable Collagen Membrane) is a sterile, pliable wound dressing made of highly purified collagen derived from porcine skin. Collagen Wound Dressing is completely absorbable and highly biocompatible. Collagen Wound Dressing is composed of porous sponge layer for the wound surface and dense film layer for protecting wound from outside.	TheraForm™ Standard / Sheet Absorbable Collagen Membrane is a sterile, pliable porous wound dressing made of highly purified collagen derived from porcine skin. TheraForm™ Standard / Sheet is completely absorbable and highly biocompatible.
Material	Pliable porous and dense scaffold agent made of highly purified porcine derived collagen	Pliable porous scaffold agent made of highly purified porcine derived collagen
Product sizes	Diameter 1 cm circle to 10 x 10cm square	40 x 30mm to 100 x 100mm square

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Comparison to Predicate Devices

There are no significant differences between the Collagen Wound Dressing and TheraForm™ Standard / Sheet currently being marketed which would adversely affect the use of the product. It is substantially equivalent to the cleared device in design, material, and its intended use.

Non-Clinical Testing

Collagen Wound Dressing was subjected to a panel of tests to assess biocompatibility in accordance with ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing and it passed the requirements of all tests. The purity and identity of Type I collagen have been confirmed by SDS-PAGE analysis and the viral inactivation and removal have been confirmed.

Clinical Testing

No clinical testing was performed for this submission.

Conclusion

The Collagen Wound Dressing is substantially equivalent to the predicate device delineated in this submission and meets the requirements for premarket notification as defined in CFR 21, Part 807. The subject device is as safe and effective as predicate medical devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 1 2012

Dalim Tissen Co., Ltd
% Kodent Inc.
Ms. April Lee
Consultant/US Agent
325 North Puente Street
Brea, California

Re: K112580
Trade/Device Name: Collagen Wound Dressing
Regulation Class: Unclassified
Product Code: KGN
Dated: May 24, 2012
Received: May 24, 2012

Dear Ms. April Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for Use

510(K) Number: N/A

Device Name: Collagen Wound Dressing

Indication for Use:

Collagen Wound Dressing is intended use for management of partial and full-thickness wounds including: pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers, tunneled / undermined wounds, surgical wound (donor sites / grafts, post-moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears), draining wounds.

Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of Surgical, Orthopedic, and Restorative Devices

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